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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/225,080	01/04/1999	JANICE AU-YOUNG	PF-0066-2-DI	2905

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/225,080

Applicant(s)
Au-Young

Examiner
Karen Canella

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1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 17, and 19-42 is/are pending in the application.
- 4a) Of the above, claim(s) 13, 17, and 19-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

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Response to Arguments

1. Claims 13, 17 and 19-42 are pending. Claims 13, 17 and 19-38 remain withdrawn from consideration. Claims 39-42 are under consideration..
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
3. The rejection of claims 39-42 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well-established utility is withdrawn after careful consideration of applicants arguments in light of the specification.
4. The rejection of claim 39-42 under 35 U.S.C. 112, first paragraph for lacking a specific substantial utility is withdrawn.
5. The rejection of claims 39-42 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons of record. Applicant argues that the examiner was at fault for not taking into account that the claim specified that said biological activity was on the surface of said stem cell. Applicant argues that the specification has made clear that a function of SCAH-2 is expression on stem cells. This has been considered but not found persuasive. In order to perform a "function" an activity has to be carried out. The stem cell expresses the SCAH-2 antigen. The SCAH-2 antigen is passive during this expression, it is the machinery of the cell which is performing a function of gene expression. An argument by applicant that the function of SCAH-2 is expression on the surface of the stem cell is not an active function that can be attributed to SCAH-2. The fact that SCAH-2 can be found on the surface of a stem cell is a property, not a function, of SCAH-2. .

Claim 39 is rendered vague and indefinite in the recitation of "biologically active fragments". The specification defines biologically active on page 5, lines 1-2 as having structural, regulator or biochemical functions of the naturally occurring SCAH. However, there is no

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description of what constitute a regulatory or biochemical function of the naturally occurring SCAH. Therefore, the metes and bound of claim 39(c) cannot be determined.

6. The rejection of claims 39 and 41 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for reasons of record of parts (a) and (B) of the rejection of section 6 of the previous Office action..

(A)As drawn to a polynucleotide comprising an amino acid sequence having at least 90% sequence identity to SEQ ID NO:2

Claims 39 and 42 are drawn in part to polypeptides comprising an amino acid sequence having at least 90% sequence identity to SEQ ID NO:2 wherein the amino acid sequence is expressed on the surface of stem cells. The specification discusses the full length SCAH-2 (SEQ ID NO:2) as being a stem cell antigen or as functioning to inhibit the activation of natural killer cells. However, the specification does not identify variants of SEQ ID NO:2 that would be expressed on the surface of stem cells, or the organs or tissues which would have said stem cells, such as prostate tissue or bone marrow. As the specification does not provide a written description of the amino acid sequences of the claimed variants to SEQ ID NO:2 that are exposed on the cell surface, one of skill in the art could not use the invention as one of skill in the art would need to where to look for said stem cells, and the specification provides no teachings as to know the organ or tissues harboring said stem cells in order to isolate said cells and determine the sequence of the variant polypeptide. Due to these reasons, one of skill in the art would be forced into undue experimentation without reasonable expectation of success in order to practice the invention as claimed. Applicant argues that the specification is enabling for where to isolate variants because the specification teaches libraries derived from cancerous tissues where SCAH-2 is found. This has been considered but not found persuasive. Given that the specification does

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not provide any objective evidence that said variants exist in the tissues from which the disclosed cDNA libraries were derived, one of skill in the art would be subject to undue experimentation without reasonable expectation of success in order to make and use the broadly claimed SCAH-2 variant polypeptides. The presence of the SCAH-2 as SEQ ID NO:2 or the cDNA encoding it, does not guarantee that the same tissues would harbor the claimed variants.

(B) As drawn to biologically active fragments of SEQ ID NO:2

Claims 39-42 are drawn in part to polypeptides comprising biologically-active fragments of SEQ ID NO:2, wherein the biologically active fragment is expressed on the surface of stem cells. It is noted for the reasons set forth in the previous office action, that the metes and bounds of claims depending on the "biological function" of a fragment of SCAH-2 is indeterminate as the metes and bound of biological activity is vague and indefinite given the lack of teachings in the specification regarding biochemical or regulatory functions of SCAH-2. Further, it would be undue experimentation without reasonable expectation of success, as firstly there is no objective evidence that full length SCAH-2 has a regulatory of biochemical activity and secondly, in the event that SCAH-2 did have a regulatory of biochemical activity there is no objective evidence that a fragment of SCAH-2 would retain said activity.

7. The rejection as drawn to part (C), section 6 of the previous Office action is withdrawn.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
January 27, 2003


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